

REMARKS

Claims 1-19 stand rejected. Applicant respectfully traverses the Examiner's rejection.

Claim Rejections – 35 U.S.C. §103

Claims 1-7, 10-13, 18, and 19 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Allen et al. ("Allen") (J. Electroanal. Chem., 178 (1984), pp. 69-86) in view of Maley et al. ("Maley") (U.S. Patent No. 5,529,676). With respect to claim 1, the rejection states that Allen discloses a metal electrode and numerous different sulfur-containing moieties for coating. However, the Examiner admits that Allen does not disclose overcoating the coating with a surfactant. Maley is cited to teach a coated electrode with an overcoating including surfactant.

Applicant respectfully traverses the rejection.

The Allen reference discloses research into the promotion of horse heart cytochrome *c* electrochemistry on a gold electrode. Fifty compounds were deposited on electrodes and tested as surface modifiers for the promotion of cytochrome *c* electrochemistry. Several of the groups were found to be useful. Allen does not disclose the use of an overcoating of any kind and one of ordinary skill in the art would have no motivation to add an overcoating to the compounds deposited on the electrodes of Allen.

Maley discloses a electrochemical sensor for the analysis of blood samples, and in particular, the measurement of glucose concentration. Maley's device includes an "active layer" (96) positioned on the electrode and composed of platinized activated carbon (PAC). The active layer can include an enzyme that participates in an electrochemical reaction.¹

¹ To reduce the affect of interfering substances, Maley can also include a semi-permeable membrane on the working electrode. This membrane permits the passage of glucose, lactate, and/or oxygen. However, the Examiner admits that Maley's disclosure of treating the membrane with a surfactant is not relevant. (Final Office Action, ¶ 24).

Maley discloses that one difficulty with the PAC layer is that it contains a hydrophobic binder and is therefore difficult to wet after fully dried. For example, Maley states at col. 15, lines 25 to 32:

The binder material, as noted above, acts to hold the components of the active layer together. To this mixture, a surfactant may be added to provide better printing flow characteristics when active layer 96 is screen printed upon conductive strip 66. An additional benefit of the surfactant is to act as a wetting agent for the sensor during use. *The active layer 96 being comprised of a hydrophobic binder becomes difficult to wet with water after it is fully dried. The surfactant facilitates this wetup.*

Thus, the surfactant is used because of the physical properties of the active layer and the method use to deposit the active layer.

The other portions of Maley which discuss a surfactant are similarly directed to a PAC layer. For example, the Examiner points to Example X as disclosing an overcoating containing a surfactant and as providing motivation for its use. Applicant respectfully disagrees, Example X is specific to a PAC layer. The first line of the Example states its purpose “To determine the effect of incorporating a surfactant in the platinized activated carbon (PAC) material...” Maley finds that the surfactant is beneficial to the storage characteristics of the active layer, but this does not suggest the use of an overcoating containing a surfactant in the disclosure of Allen. Example X only suggests the use of a surfactant in a PAC layer in an electrochemical cell.

The Examiner relies on a particular statement in Example X, “[t]he addition of the surfactant to the PAC, active and inactive layers, aids in sensor wetup.” (col. 31, lines 4-6). However, a careful reading of the text reveals that this passage is only discussing PAC “active and inactive layers” and their use in a “sensor.” The commas, which set off the phrase “active and inactive layers,” modify the term “PAC.” The cited phrase thus refers to the addition of surfactant to PAC containing layers (i.e., active layer 96 and inactive layer 92²). Thus, properly

² The term “inactive layer” is discussed in Example III, which states that the “inactive layer” comprises PAC and includes “5.0 grams of binder resin.”

read, any suggestion concerning the use of surfactants in teachings of the Maley reference is limited to PAC containing layers in an electrochemical cell.

The Examiner has thus failed to present a *prima facie* case of obviousness for the combination of Allen and Maley. The Maley reference is directed to a different device, used in a different way, for the analysis of a different analyte. The surfactants in Maley are used in a PAC/binder containing layer in an electrochemical sensor. Accordingly, the teachings of Maley are not applicable to the Allen reference.

Allen is concerned with the electrochemistry of cytochrome *c*, while Maley is directed toward a glucose sensor having a membrane. The suggestion in Maley to apply a surfactant to a active layer to assist with wetting up, does not provide any motivation to apply a surfactant to a device lacking a PAC/binder material (i.e., the device of Allen). The application of a surfactant would provide no benefit to the electrode of Allen and one of ordinary skill in the art would thus have no reason to apply the surfactant of Maley to Allen.

Moreover, since Maley's teaches that the application of a surfactant assists with *glucose* monitoring, and the PAC active and inactive layers are adapted for use with enzyme reactions, there is no reasonable expectation of success. Allen has no equivalent of the PAC active layer. Certainly the Examiner is not suggesting the addition of a PAC layer to the device of Allen, however, it would be improper to choose the surfactant from the PAC layer alone and add it to the device of Allen. Accordingly, one skill in the art would have no reason to believe that the teachings of Maley would improve the electrode of Allen and assist with the promotion of cytochrome *c* electrochemistry.

Moreover, Maley teaches that the surfactant is incorporated in the PAC rather than applied in an *overcoating* to a coating. The choice of language, i.e., incorporating, is specific and requires the surfactant to be mixed with the PAC layer. Moreover, the PAC layer is not applied on top of another coating, instead it is applied to the electrode. Accordingly, the portion of Maley cited by the Examiner does not relate to an "overcoating."

The Examiner reads the term “overcoating” so broadly that it is given no meaning. In particular, the Examiner states “Mixing the surfactant in with the powdered electrode material would result in a surfactant coating not only between all the particles of the electrode, but also a coating over the top of the electrode.” Applicant respectfully disagrees. Nowhere does Maley teach or disclose the surfactant could extend *above the PAC layer*. The overcoating of claim 1 is positioned at least partially *over* the sulfur moiety containing coating.

For example, Applicant’s disclosure states that in one embodiment,

The surfactant layer can be applied after the application of the sulfur containing layer or at the same time as the sulfur containing layer, for example the sulfur containing species and the surfactant can be placed in a coating bath into which the electrode material is immersed. Due to the higher affinity of the sulfur containing species for the electrode material it will bind to the electrode surface in preference to the surfactant, *leaving the surfactant in a layer over the sulfur containing layer*.

Page 4, lines 8-13. (emphasis added).

One of ordinary skill in the art would thus have no reason to believe that the addition of a surfactant, as disclosed in Maley, would assist with the promotion of cytochrome *c* electrochemistry as taught in Allen. The only basis for an obviousness type rejection based on the combination of Allen and Maley would be improper hindsight gleaned from Applicant’s own specification. Accordingly, Applicant respectfully requests withdrawal of the rejection.

The rejection based on Schlerich in view of Maley

Claims 1, 2, and 6 – 19 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Schlereth et al. (“Schlereth”) (Electroanalysis 1995, 7 (1), pp. 46-54) in view of Maley. The rejection states that Schlerich discloses a coated metal electrode where the metal electrode comprises a coating of a sulfur containing moiety comprising cysteine. However, the Examiner admits that Schlerich does not disclose the use of an overcoating of a surfactant and cites Maley to remedy the deficiencies of Schlereth.

Applicant respectfully traverses the rejection.

Schlereth discloses surface modified electrodes (SME) able to catalyze the oxidation of NADH. As part of the surface modification, amino-containing sulfur compounds, cystamine, and cysteine were used. The electrocatalytic oxidation of NADH at different mediator-SMEs was then monitored by cyclic voltammetry. Schlereth, which is cited to teach a sulfur containing moiety comprising cystine.

As discussed above with respect to the combination of Allen and Maley, Maley's disclosure is specific to a surfactant positioned in a PAC layer containing a binder and is used in combination with an electrochemical sensor. Conversely, Schlereth includes no such layer or any PAC/binder.

One of ordinary skill in the art would have no motivation to apply the teachings of Maley, which discloses a blood glucose sensor with a PAC layer, to the Schlereth reference. The Maley reference discloses a different device, having a different structure, adapted to investigate a different analyte. Even if a surfactant were added to the SME of Schlereth, there is no reasonable expectation of success. Oxidation of NADH is a much different chemical process from the detection and analysis of glucose. If a surfactant were added, it is unclear how the surfactant would effect the device of Schlereth.

Moreover, even if these references could be combined, the combination would fail to teach the limitations of Applicant's claims. As discussed above, Maley does not disclose applying an overcoating of a surfactant to a coating comprising a sulfur containing moiety. Instead, a surfactant is applied to a membrane or incorporated into a platinized activated carbon material. Thus even if Schlereth and Maley could be combined (which they cannot), the combination would lack an overcoating. Accordingly, Applicant believes the combination of Maley, and Schlereth is improper and respectfully requests withdrawal of the rejection.

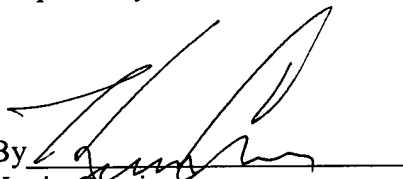
Applicant believes that independent claims 1, 18, and 19 distinguish over the cited prior art and that the dependent claims are allowable at least because they depend from an allowable base claims. Applicant respectfully requests withdrawal of all the outstanding rejections.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. However, should any outstanding issues remain, Applicant asks that the Examiner please contact the undersigned Attorney for Applicant.

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Respectfully submitted,


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